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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,917	01/24/2001	Alain P. Vicari	SF0896K	5028

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SCHERING-PLOUGH CORPORATION  
PATENT DEPARTMENT (K-6-1, 1990)  
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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT

PAPER NUMBER

1632

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/768,917</b>	Applicant(s) <b>Vicari</b>
	Examiner <b>Anne Marie Wehbé</b>	Art Unit <b>1632</b>
		
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>		
<b>Period for Reply</b>		
<b>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</b>		
<ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.138 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>		
<b>Status</b>		
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Sep 24, 2002</u>		
2a) <input type="checkbox"/> This action is FINAL.      2b) <input checked="" type="checkbox"/> This action is non-final.		
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.		
<b>Disposition of Claims</b>		
4) <input checked="" type="checkbox"/> Claim(s) <u>21-36 and 69</u> is/are pending in the application.		
4a) Of the above, claim(s) _____ is/are withdrawn from consideration.		
5) <input type="checkbox"/> Claim(s) _____ is/are allowed.		
6) <input checked="" type="checkbox"/> Claim(s) <u>21-36 and 69</u> is/are rejected.		
7) <input type="checkbox"/> Claim(s) _____ is/are objected to.		
8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.		
<b>Application Papers</b>		
9) <input type="checkbox"/> The specification is objected to by the Examiner.		
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.		
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.		
<b>Priority under 35 U.S.C. §§ 119 and 120</b>		
13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received.		
14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.		
15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.		
<b>Attachment(s)</b>		
1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)		
4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____		
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		
5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)		
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____		
6) <input type="checkbox"/> Other: _____		

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## DETAILED ACTION

Applicant's response to the restriction requirement received on 9/24/02 has been entered.

Claims 67-68 have been canceled. Claims 21-36 and 39 are pending in the instant application.

Applicant's election without traverse of the subject matter of group XIII, claims 21-36 and 69, is acknowledged. Please note, the restriction requirement is still deemed proper and is therefore made FINAL. Claims 21-36 and 39 are currently under examination. An action on the merits follows.

Please note that the examiner of record and the art unit for this application have changed, see page 6.

### *Priority*

Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon application EP 0 974 357 filed on 7/16/98. However, a claim for priority under 35 U.S.C. 119 (a)-(d) **cannot** be based on said application since the United States application was filed more than twelve months after the **filings date** of the foreign application. Thus, applicant is denied priority to EP 0 974 357. The **effective priority date** of the application is the actual filing date of instant application, 1/24/01.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-36 and 69 are rejected under 35 U.S.C. 102(a) as being anticipated by EP 0 974 357, 1/26/00, hereafter referred to as Caux et al. As noted above, applicant's have been denied priority to this foreign application since the application was filed more than twelve months before the filing of the instant application. In addition, while the foreign application was published less than 1 year before the filing of the instant application, the inventive entity of the EP document and the instant application are not the same. Specifically, the inventors Beatrice Vanbervliet, Serge Lebecque, and Marie-Caroline Dieu listed in the EP document are not listed as instant inventors. Likewise, the instant inventor Drake LaFace is not listed on the EP document. Therefore, since the inventive entities of the EP document and the instant application as different, the EP document qualifies as prior art under 102(a).

The applicant claims methods of enhancing an immune response in a mammal comprising administering MCP-4 alone or in combination with an antigen. The applicant further claims said

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methods wherein the MCP-4 is administered in the form of a vector, wherein the antigen is a tumor antigen, or viral antigen, or wherein the MCP-4 is administered intradermally or intramuscularly. The applicant also claims said methods wherein a non-methylated CpG “activating agent” is administered with the MCP-4, or wherein the MCP-4 is co-administered with GM-CSF and IL4

Caux et al. teaches methods of using a chemokine such as MCP-4 for directing the migration of dendritic cells to lymphoid organs in vivo in order to increase immune responses (Caux et al., columns 4-6, and 18-19). In particular, Caux et al. claims delivery of MCP-4 as a protein or a nucleic acid, alone or in combination with a viral, or tumor antigen (Caux et al., column 6, and columns 18-19, claims 1-5, 11-14). Caux et al. further teaches the administration of non-methylated CpG as an “activating agent”, the co-administration of GM-CSF and IL4, and the administration of the MCP-4 chemokine intradermally or intramuscularly (Caux et al., column 19, claims 17-20). Thus, by teaching all the elements of the claims as written, Caux et al. anticipates the instant invention as claimed.

Claims 21-23, 35, 36, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/14573, 4/9/98, hereafter referred to as Luster et al. The applicant claims methods of enhancing an immune response in a mammal comprising administering the MCP-4 chemokine. The applicant further claims said methods wherein the MCP-4 is administered in the form of a vector, and wherein a non-methylated CpG “activating agent” is administered with the MCP-4.

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Luster et al. teaches the administration of human MCP-4 in the form of a protein or a nucleic acid vector in order to stimulate immune responses in a mammal (Luster et al., pages 4-5, particularly page 5, lines 9-12). Luster et al. also teaches the construction and use of both bacterial and eukaryotic vectors encoding MCP-4 (Luster et al., pages 31-32). Please note that while Luster et al. does not specifically teach that the nucleic acid vectors encoding MCP-4 contain unmethylated CpGs, the presence of unmethylated CpGs in vector DNA prepared from bacteria is an inherent result of DNA replication in bacteria. Therefore, the nucleic acid vector encoding MCP-4 inherently contains unmethylated CpGs. Thus, by teaching all the limitations of the claims as written, Luster et al. anticipates the instant invention as claimed.

***Claim Rejections - 35 USC § 112***

. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term “activating agent” is confusing as it is unclear what substance or effect the agent is intended to “activate”. As such the metes and bounds of the claims cannot be determined.

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No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Fri from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D  
PRIMARY EXAMINER

